REMARKS

1. Amendments to the Specification.

Applicants have corrected typographical errors in the specification.

In line 8, page 20, "NH_3" is replaced with "NH_2". The chemical structure of the KPV dimer is shown in Fig. 16 (p. 7, ll. 8-9 & Fig. 16) and the carboxyl terminal of Val is amidated (p. 20, l. 7 & Fig. 16). Accordingly, the carboxyl terminal of Val ends with "NH_2".

In line 22, page 23 to line 1, page 24, the term "NH_2-Lys-Pro-Val-Ac-Cys-Cys-Ac-Val-Pro-Lys-NH_2 (the "KPV dimer")" is replaced with the term "NH_2-Val-Pro-Lys-Ac-Cys-Cys-Ac-Lys-Pro-Val-NH_2 (the "KPV dimer")". Applicants note Fig. 16 shows the chemical structure for the amino acid sequence VPKCCKPV, known as the "KPV dimer" (p. 7, ll. 8-9 & Fig. 16). Further, the KPV dimer can be chemically represented as NH_2-Lys-Pro-Val-Ac-Cys-Cys-Ac-Val-Pro-Lys-NH_2 (P. 20, ll. 7-8). Accordingly, the KPV dimer in the instant application denotes the structure of NH_2-Val-Pro-Lys-Ac-Cys-Cys-Ac-Lys-Pro-Val-NH_2, rather than NH_2-Lys-Pro-Val-Ac-Cys-Cys-Ac-Val-Pro-Lys-NH_2.

By the same token, in line 9, page 24, the term "KPVCCVPK (the "KPV dimer")" is replaced with the term "NH_2-Val-Pro-Lys-Ac-Cys-Cys-Ac-Lys-Pro-Val-NH_2 (the "KPV dimer")".

In lines 19 and 21, page 32, the term "SYSMEHFRWGKP" is replaced with the term "SYSMEHFRWGKPV". The support for the correction can be found in line 14, page 4 of the application.

In light of the foregoing, the above corrections find respective support in the specification and therefore do not constitute new matter.

2. 37 C.F.R. §§ 1.821- 1.825.

The Office Action asserted that the application fails to comply with the requirements of 37 C.F.R. §§ 1.821- 1.825.

Applicants are submitting a Sequence Listing which is prepared in accordance with 37 C.F.R. §§ 1.821- 1.825. The Sequence Listing is shown in the attached paper copy as well as the attached computer readable copy. Applicants have also amended the specification to include the requisite sequence identifiers.

Applicants hereby state that the submission of the Sequence Listing does not include new matter and that the content of the sequence listing information recorded in the computer readable copy is identical to the written sequence listing in the paper copy.

3. Rejection of Claims 13, 15-33 under 35 U.S.C. § 112 ¶ 2

Claims 13 and 15-33 were rejected under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action asserted that "a KPV" or "a KPV composition" is vague and indefinite.

In the telephonic interview conducted on July 16, 2003 between Examiner Jeffery Parkin, Ph.D. and Applicants' patent counsel (the "July 16 Interview" hereinafter), Applicants were advised that the replacement of the term "a KPV" with the term "a KPV tripeptide" may overcome the rejections.

Applicants have amended the claims to be directed to "a KPV tripeptide" or "a KPV tripeptide composition" wherein the composition comprises a KPV tripeptide and a

carrier. Accordingly, Applicants respectfully request that the rejections be reconsidered and withdrawn.

4. Rejection of Claims 24-33 under 35 U.S.C. § 112 ¶ 2

Claims 24-33 were rejected under 35 U.S.C. § 112 ¶ 2 for being indefinite. In particular, the Office Action asserted that it is not readily manifest how the claimed methodology "enhances" the killing of any given pathogen.

Applicants have removed the term "enhancing the killing of a pathogen" and therefore made the rejection moot. Applicants respectfully request that the rejection be withdrawn.

5. Rejection of Claims 13, 15-18 and 20-33 under 35 U.S.C. § 112 ¶ 2

Claims 13, 15-18 and 20-33 were rejected under 35 U.S.C. § 112 ¶ 2 being vague and indefinite. In particular, the Office Action asserted that the claims simply state that a "KPV" composition is administered to a patient and that claims fail to include all the salient steps that are necessary to perform the claimed methodology.

Applicants respectfully traverse. It is well settled that a claim is incomplete under 35 U.S.C. § 112 ¶ 2 if the claim does not recite any steps. M.P.E.P 2173.05(q). See also, *Ex parte Erlich* 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

In *Ex parte Erlich*, a claim, which reads" a process for using monoclonal antibodies of Claim 4 to isolate and purify human fibroblast interferon", was held to be indefinite because it merely recite a use without any active, positive steps delimiting how this use is actually practiced. Id. While it was held that a method claim should at least recite a positive, active step, it was also held that a claim need not recite all of the operation details. Id.

Unlike the claim in *Ex parte Erlich*, the claims of the present application recite one active, positive step, which comprises "administering" a KPV tripeptide or a KPV tripeptide composition to an individual. Applicants note that claims need not recite all of the operation details.

Accordingly, since the claims recite an active, positive step, the rejection of the claims under 35 U.S.C. § 112 ¶ 2 being vague and indefinite is untenable. Applicants respectfully request that the rejection be reconsidered and withdrawn.

6. Rejection of Claims 13 and 15-33 under35 U.S.C. § 112 ¶ 1 .

Claims 13 and 15-33 were rejected under § 112 ¶ 1 for allegedly failing to satisfying the written description requirement. In particular, while the Office Action conceded that the disclosure supports the KPV's anti-microbial activity towards *Staphylococcus* and *Candida*, the Office Action asserted that the specification fails to provide adequate support for any given pathogen.

During the July 16 Interview, Applicants were advised to point out description in the specification regarding the mechanism of KPV in inhibiting pathogens' infection. Applicants were further advised to submit a 1.132 Affidavit to support the cross phyla activity of KPV in inhibiting pathogens' infection. It was also advised that the support for a mechanism of action for inhibition of microbes in general and the 1.1321 Affidavit may overcome the rejection.

Support for the cross phyla and for cross Kingdom activity of the KPV tripeptide can be found in the specification at pages 16, 18 and 25-30. In particular, the specification includes support for inhibition of *Candida albicans* (contained in the Kingdom, Fungi; Phylum Zygomycota) and *Staphylococcus aureus* (contained in the

Kingdom; Prokaryotae; Phylum Omnibacteria). This disclosure alone demonstrates a cross Kingdom activity of the KPV tripeptide.

Support for cross Kingdom activity is also found in the mechanism of action of KPV. Without being limited by any theoretical explanation, the antimicrobial effect of KPV may be caused by the accumulation of cAMP (p. 29, l. 22 to p.30, l. 2). As known in the art, cAMP is a common component of living cells including all pathogens. A sufficient increase in cAMP leads to cell death. By showing that bacteria as in *Staphylococcus aureus* and yeast or fungi as in *Candida albicans* have been inhibited in their growth through the use of KPV, the specification reasonably conveys to one skilled in the art that Applicants, at the time the application was filed, had possession of the claimed invention which is directed to the pathogen genus.

The cross phyla, antimicrobial activity of KPV is further supported in the 37 C.F.R. § 1.132 Affidavit of inventor James M. Lipton, Ph.D., as attached herein.

In light of the foregoing, the disclosure in the specification and Dr. Lipton's Affidavit satisfy the written description requirement. It is respectfully requested that the § 112 ¶ 1 rejection be reconsidered and withdrawn.

7. Rejection of Claims 13, 15-33 under 35 U.S.C. § 103(a)

Claims 13 and 15-33 were rejection under 35 U.S.C. § 103(a) as being obvious over Lipton (1992) in view of Saag (1997).

Applicants were advised in the July 16 Interview that the rejection may be overcome if the term "treating" is amended to the term "inhibiting".

Applicants have replaced the term "treating" with the term "inhibiting". The amended claims are now directed to "a method for inhibiting opportunistic infections".

Since Lipton merely teaches the treatment of pyrexia and inflammation using KPV and Saag teaches the clinical manifestations associated with HIV infection, the combination of Lipton and Saag does not render the claimed invention which is directed to a method of inhibiting opportunistic infections.

Accordingly, Applicants respectfully request that the rejections be reconsidered and withdrawn.

CONCLUSION

In light of the foregoing, Applicants have placed the application in condition for allowance. Therefore, a Notice of Allowance is respectfully requested.

Respectfully submitted,
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